IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

Plaintiff,

Civil Action No. 1:24-cv-1524-DAE

VS.

JURY TRIAL DEMANDED

ALNYLAM PHARMACEUTICALS INC. AND ALNYLAM U.S., INC.

Defendants

ALNYLAM'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS FOR IMPROPER VENUE OR IN THE ALTERNATIVE TRANSFER UNDER RULE 12(b)(3)

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I. INTRODUCTION

Alnylam is a recognized pioneer in the development of RNA therapeutics, engaged in the research of innovative therapies that utilize critical lipid nanoparticle ("LNP") technology for the safe and effective transport of RNA to human cells. Alnylam utilized its novel LNP technology to develop the world's first approved RNAi therapeutic—ONPATTRO®—which treats a rare and rapidly progressing genetic disease known as hereditary ATTR amaloidosis (hATTR). Alnylam's headquarters is in Cambridge, Massachusetts, where the majority of its U.S. employees work in physical office and laboratory facilities.

Plaintiff's opposition confirms that venue is improper in the Western District of Texas ("District"). Plaintiff concedes it cannot establish venue pursuant to the first prong of Section 1400(b) and fails to provide credible evidence of any of the multiple elements the second prong requires. First, Plaintiff incorrectly contends that Alnylam's sponsorship of clinical trials in this District and/or a handful of remote employees who live in this District are sufficient to establish venue. Courts have expressly found, however, that sponsorship of a clinical trial, including the control of the study protocol, does not establish a place of business for purposes of venue. Plaintiff fails to cite anything to the contrary. Second, the presence of a handful of Alnylam remote employees in this District is insufficient to show that Alnylam maintains a regular and established place of business in the District. If it were, Alnylam (and every company that employs sales representatives to sell products throughout the United States) would be subject to venue in virtually every judicial district. That result is not consistent with *TC Heartland* and its progeny.

Although the case should be dismissed for improper venue, Plaintiff's opposition also confirms that the District of Massachusetts is clearly a more convenient forum than this District. First, Plaintiff does not identify any connections between itself and this District, given that the named inventors relied on by Plaintiff live and work in the Southern District of Texas. By contrast,

there is no dispute that Alnylam's corporate headquarters and the majority of its U.S. employees are located in the District of Massachusetts. Second, Plaintiff does not dispute that the vast majority of key Alnylam witnesses (including many who are no longer employed by Alnylam), location of digital and hard copy records, and custodians of those records reside in the District of Massachusetts. In short, the District of Massachusetts has significant connections to the events forming the basis for Plaintiff's patent infringement allegations.

II. VENUE IS NOT PROPER IN THE WESTERN DISTRICT OF TEXAS

Plaintiff admits that Alnylam does not "reside" in this District. Thus, whether venue is proper hinges on whether Plaintiff has met its burden of showing Alnylam has a "regular and established place of business" in this District. Plaintiff relies on clinical trial sites and the presence of a few remote employees in this District. For the reasons discussed below, neither is sufficient to establish this District as an Alnylam "regular and established place of business."

A. Alnylam-Sponsored Clinical Trials in the District Do Not Establish Venue

Plaintiff cites no case law for its proposition that clinical trials, sponsored by a defendant but conducted by third parties, are sufficient to establish a regular and established place of business. Indeed, courts that have considered this issue have expressly found "control" over a clinical trial protocol insufficient to establish a place of business. In *Regents of Univ. of Minn. v. Gilead Scis., Inc.*, the Court found that the University's allegations that Gilead had "control over dozens of clinical trials in Minnesota" did not establish venue, because control of the protocol of the studies was not evidence that "Gilead owns or controls the physical space in which the trials are held." 299 F. Supp. 3d 1034, 1044 (D. Minn. 2017). Similarly, in *Bausch Health Ireland Ltd. v. Mylan Labs. Ltd.*, the Court found that clinical trials "conducted by third parties—which may be sponsored by or in collaboration with one or more Defendants or their affiliates—do not amount to a physical place of business." 2022 WL 683084, at *7 (D.N.J. Mar. 8, 2022). That court found

that Bausch had not submitted evidence, let alone alleged, that the defendant "(i) owns or leases any of the clinical trials' locations; (ii) employed the personnel used to run the clinical trials; (iii) are identified by name on the building where the clinical trials are run; or (iv) identify the address of the clinical trial as a place of business." *Id*.

As in *Bausch*, while Alnylam sponsors clinical trials in this District (and throughout the country), including the clinical trials in Plaintiff's Exhibits A-D, it (i) does not own or lease the clinical trials' locations, (ii) does not employ the personnel used to run the clinical trials, (iii) is not identified by name on any building where the clinical trials are run; or (iv) does not identify the address of the clinical trials as a place of business. D.I. 21-1, ¶¶ 21-24; Second Declaration of Steve Bossone ("Bossone Second Decl."), ¶ 6.

Plaintiff's statement that "Alnylam has designated their employee as 'Alnylam Medical Director" on Clinicaltrials.gov fares no better. D.I. 24, 5. Alnylam's Medical Director is based at Alnylam's headquarters in the District of Massachusetts and has responsibility for numerous clinical trial locations across the country. Bossone Second Decl. ¶ 7. As explained in Alnylam's opening brief, the clinical trials are administered by third parties at clinical sites owned and controlled by medical institutions—not employees of Alnylam. D.I. 21, 6-7. Plaintiff's argument that Alnylam's contracts with third-party CROs would show that Alnylam "fully controls the trials" (D.I. 24, 6) is futile and misapprehends the law. "While [Alnylam] may indeed closely control the protocol of these studies, and the presence of its drugs, there is no evidence that [Alnylam] owns or controls the physical space in which the trials are held." *Gilead*, 299 F. Supp. 3d at 1044. No amount of venue discovery will change these facts.

B. A Handful of Remote Employees in the District Does Not Establish Venue

Out of Alnylam's over two thousand employees, Plaintiff points to three remote, field-based Alnylam employees, Heather Smith, Kimberly McAlarney, and Jane Regan, to argue

Alnylam has a "regular and established place of business" in this District. D.I. 24, 6-8.

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Alnylam's Medical Science Liaisons, including Ms. Regan, are not required to live within this District, or even within the State of Texas. *See* D.I. 21, 5-6; Bossone Second Decl. ¶ 8. While Alnylam's sales personnel, including Ms. Smith and Ms. McAlarney are assigned to specific territories (*e.g.*, Austin and San Antonio), Alnylam does not: (i) use these employees' homes to store any inventory so they can be distributed or sold from that place; (ii) engage any secretarial services physically located in the district to perform certain tasks; or (iii) own or lease any portion of its employees' homes or pay any part of their rent in the District. Expense reimbursements and administrative support for sales personnel are provided from outside the District. D.I. 21-1, ¶ 12; Bossone Second Decl. ¶ 9-10.

These facts are similar to *Cray*, where the court found that that the facts "do not show that Cray maintains a regular and established place of business in the Eastern District of Texas; they merely show that there exists within the district a physical location where an employee of the defendant carries on certain work for his employer." *In re Cray Inc.*, 871 F.3d 1355, 1366 (Fed. Cir. 2017). In *Cray*, the court noted its finding was consistent with the Fourth and Seventh Circuits in holding that sales employees working at home did not constitute a regular and established place of business of defendants, where they did not stock any product or hold their homes out as the defendant's place of business. *Id.* Likewise, the facts here cannot support a finding that Alnylam maintains an established a place of business in this District. *See, e.g., Silicon Tech., Inc. v. United Refractories, Inc.*, 632 F. Supp. 1, *2 (W.D. Pa. 1985) ("Where a corporation employs sales representatives within a district without owning, leasing, or controlling any real property within

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¹ In his Second Declaration, which reflects further internal investigation, Mr. Bossone provides additional clarity regarding the territories covered by Ms. Smith and Ms. McAlarney.

the district, as here, courts have been reluctant to find a regular and established place of business.").

Plaintiff's reliance on the *RegenLab* case is misplaced. There the defendant had an entirely remote workforce, causing the court to conclude that, "home offices constitute a primary physical location for Eclipse's business." *RegenLab USA LLC v. Estar Techs. Ltd.*, 335 F. Supp. 3d 526, 549 (S.D.N.Y. 2018). Here, Alnylam's office headquarters and affiliated physical locations are in Massachusetts, where the majority of its U.S.-based employees work in physical office, laboratory and manufacturing facilities. D.I. 21-1, ¶ 6, 9. It also maintains several other physical locations, but none in this District. D.I. 21-1, ¶ 8. Therefore, unlike the scenario in *RegenLab*, a relative comparison of the "nature and activity of the alleged place of business of [Alnylam] in the district in comparison with that of other places of business of [Alnylam] in other venues" demonstrates that Alnylam does not have "a business model whereby many employees' homes are used by the business as a place of business of the defendant." *Cray*, 871 F.3d at 1364, n.l.

III. THIS CASE SHOULD BE TRANSFERRED TO THE DISTRICT OF MASSACHUSETTS

There is no dispute that this case could have been brought in the District of Massachusetts. Although this case should be dismissed for lack of venue, Plaintiff's arguments regarding the private and public factors for transfer confirm that Alnylam has met its burden of showing that the District of Massachusetts is "clearly more convenient." *HD Silicon Sols. LLC v. Microchip Tech. Inc.*, 2021 WL 4953884 at *2 (W.D. Tex. Oct. 25, 2021).

A. The Cost of Attendance for Willing Witnesses Favors Transfer

Plaintiff incorrectly asserts that Alnylam does not identify any specific employee with relevant knowledge in Massachusetts. D.I. 24, 10. Alnylam identified at least eight specific Alnylam employees who reside in the District of Massachusetts, and 31 specific individuals located within the District of Massachusetts who have relevant knowledge regarding the research,

development, and testing of ONPATTRO®, responsibility for the leadership of the ONPATTRO® team, or attended the alleged 2007 meeting. D.I. 21, 11-12; D.I. 21-1, ¶¶ 16, 19-20, 27. As to the Alnylam former employees, although Alnylam has no way of knowing whether such individuals would be willing witnesses, they are not subject to the subpoena power of this Court for trial. Regardless, all these Massachusetts-based individuals have knowledge relating to the product accused of infringement in this case and would be inconvenienced in having to travel to Texas. Plaintiff's reliance on *Vervain LLC v. Kingston Tech. Co.*, No. 24-cv-254, D.I. 56 (W.D. Tex. Jan. 28, 2025) is misplaced. In *Vervain*, the moving party had not identified *any specific employees* who had relevant and material information.

Plaintiff points to Mr. Vest to quibble that Alnylam "does not say what Mr. Vest does or why his duties are material to the case." D.I. 24, 10.² As Mr. Vest is the only current Alnylam employee who led the ONPATTRO® development team, he has corporate knowledge relating to the clinical development strategy and clinical trial execution for ONPATTRO®. Bossone Second Decl. ¶ 11; see also Ex. F. Plaintiff's reliance on Jawbone Innovations, LLC v. Apple Inc., No. 6:21-CV-00984-ADA, D.I. 103 (W.D. Tex. Oct. 5, 2022) is misplaced. In Jawbone, the court "explained its concerns with Apple's repeated use of [its finance manager] as an unreliable venue declarant in [another case]." Id., 9-10. (emphasis added). The court further noted that Apple's declarant needed to investigate an enormous amount of accused Apple products. Id., 11. None of these facts are present here. Mr. Bossone is not a repeatedly used, unreliable venue declarant and

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² Plaintiff also takes issue with the Bossone declaration "not explain[ing] what role *any* Alnylam attendees played at the [2007] meeting." D.I. 24, 11. However, it is Plaintiff – not Alnylam – that alleges the 2007 meeting is relevant to its patent infringement claims. To the extent Plaintiff wishes to obtain testimony from the individuals in attendance on behalf of Alnylam, the two attendees who are currently employed by Alnylam reside in the District of Massachusetts and would be inconvenienced in having to travel to Texas.

ONPATTRO® is the only accused product identified in Plaintiff's Complaint.

In stark contrast, Plaintiff fails to identify any Alnylam-affiliated individuals in this District whose testimony would be relevant to this case. Instead, it identifies only two named inventors of the '717 Patent from MD Anderson, both of whom reside in the Southern District of Texas. Plaintiff also ignores the remaining two inventors who do not reside within the State but appear to live in Virginia and Chile – where travel would be equally inconvenient to either district. D.I. 21, Ex. C-D. The presence of the two Texas-based scientists from MD Anderson "cannot overcome the immense inconvenience that the majority of relevant witnesses would face if this case were to be tried in WDTX." *In re Samsung Elecs. Co., Ltd.*, 2023 WL 8642711, *2 (Fed. Cir. 2023).

B. The Relative Ease of Access to Sources of Proof Favors Transfer

It is well established that in patent cases, the location of the defendant's documents is the most important factor regarding relative ease of access to sources of proof. D.I. 21, 10. Plaintiff cites no case law that the analysis should be different in this case.

Plaintiff relies on *Beijing Meishe Network Tech. Co., Ltd. v. Tiktok Inc.*, 2023 WL 2903978 (W.D. Tex. Apr. 11, 2023) to argue that because Alnylam's documents are digitized, the location of these documents is not a significant factor in the transfer analysis. That case involved source code that the defendant alleged was only accessible in California but was revealed under deposition to be accessible in Irving, Texas. *Id.*, *8. The court found this factor unpersuasive for transfer to the Northern District of California. *Id.* By contrast, discovery in this case is likely to involve lab notebooks, experiment records, meeting minutes, presentations and email records, among other things. While Alnylam's records are primarily digitized, the digital records and their custodians are in the District of Massachusetts. D.I. 21, 11; *In re Google LLC*, 2021 WL 5292267, *2 (Fed. Cir. Nov. 15, 2021) (for digitized documents, courts should consider both "the location of servers where documents are stored" and "the location of document custodians and location where

documents are created and maintained."). Moreover, Plaintiff fails to identify any physical evidence located in this District that would make transfer a burden. Indeed, Plaintiff admits that the "University's records are located in Texas or are digitized." D.I.24, 13. This factor weighs in favor of transfer to the District of Massachusetts.

C. The Availability of Compulsory Process Favors Transfer

Plaintiff suggests that this factor should be entitled to less weight because Alnylam has not specifically established that any of the identified individuals will be unwilling witnesses. Not so. Alnylam identified numerous former employees with specificity, including their knowledge relating to the research, development and testing of the accused product, ONPATTRO[®]. D.I. 21, 11-12; D.I. 21-1, ¶¶ 16, 19, 27. Of the 31 Alnylam individuals specifically identified, 19 no longer work for Alnylam and are thus not within Alnylam's control. Id. For example, Eric Green and Rena Denoncourt are former Alnylam employees who had responsibilities in leading the ONPATTRO® development team. D.I. 21-1, ¶ 19. Both Mr. Green and Ms. Denoncourt currently reside in Massachusetts. Ex. G. Mr. Green was employed by Alnylam from 2015 through 2024 and Ms. Denoncourt was employed at Alnylam from 2007 through 2024. Id. As such, both would have knowledge relating to the development and commercialization of ONPATTRO®. Both Mr. Green and Ms. Denoncourt would be outside the subpoena power of this District but would be accessible in the District of Massachusetts. See, e.g., Uniloc USA Inc. v. Box, Inc., 2018 WL 2729202, *3 (W.D. Tex. June 6, 2018) (The focus of this factor is "not whether a witness may become an unwilling witness, or whether a court may need to invoke its subpoena power; rather, the focus is on the availability of process to secure attendance of a witness if need be.").

D. <u>The Other Practical Problems Factor Favor Transfer</u>

Plaintiff does not dispute that this case is in its early stages and there would be no practical problems in transfer. As explained in Alnylam's opening brief and above, the expense and ease

of getting the vast majority of key witnesses to this District favors transfer. D.I. 21, 12-13.

E. The Public Interest Factors Favor Transfer

Plaintiff makes a misguided suggestion that the "local interest" factor weighs against transfer because "the crux of the complaint is that Alnylam took advantage of the University of Texas, in Texas." D.I. 24, 14-15. Plaintiff's Complaint alleges Alnylam's ONPATTRO® infringes the '717 Patent. D.I. 1, ¶¶ 20-22. It is black letter law that to prove infringement of a patent claim, a patentee must show that an accused product meets every limitation of the claim. *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1376 (Fed. Cir. 2005). Thus, the question to be decided is not "whether Alnylam developed Onpattro in Massachusetts or whether Drs. Sood and Lopez-Berestein made the key breakthrough in Texas" as Plaintiff argues (D.I. 24, 14-15), but rather, whether the accused product, ONPATTRO®, meets every limitation of the asserted claims. Plaintiff does not, and cannot, dispute that the research and development of ONPATTRO® took place in Cambridge, Massachusetts. Nor can it dispute that the vast majority of Alnylam's relevant witnesses are residents of that district. D.I. 21, 13. As explained in Alnylam's opening brief, the local interest factor favors the District of Massachusetts because it has significant connections to the events forming the basis for the patent infringement allegations. *Id.*, 13-14.

IV. PLAINTIFF IS NOT ENTITLED TO VENUE DISCOVERY

Plaintiff did not submit a motion seeking leave for venue discovery. Even if the Court were inclined to consider some limited venue discovery, Plaintiff does not even mention, much less satisfy its burden of showing the necessity for venue discovery in this District. "As the party opposing transfer and requesting discovery, the plaintiffs bear the burden of demonstrating the necessity of discovery." *ICharts LLC v. Tableau Software, LLC*, 2024 WL 2305214, *4 (W.D. Tex. May 21, 2024) (citing *Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 434 (5th Cir. 2014)). A district court may deny venue discovery "when there is no indication of fraud or misconduct in

the defendant's affidavits, and there is no reason to believe that additional information would alter the outcome." *DH Int'l Ltd. v. Apple Inc.*, 2024 WL 3748039, *2 (W.D. Tex. July 18, 2024). Plaintiff does not address those two factors for obtaining venue discovery.

Plaintiff's sole complaint appears to rest on the fact that Alnylam relies on the testimony of one declarant—Mr. Bossone. But Plaintiff's opposition fails to identify any fraud or misconduct in Mr. Bossone's declaration. Courts have denied venue discovery in the absence of fraud or misconduct. *Optic153 LLC v. Thorlabs Inc.*, 2020 WL 3403076, *1 (W.D. Tex. June 19, 2020). Plaintiff also fails to identify any additional information altering the venue analysis that is not already addressed by Mr. Bossone. Ordering "the parties to complete venue discovery when it would not affect the Court's venue analysis would be an inefficient use of judicial resources—and of party resources." *DH Int'l Ltd.*, 2024 WL 3748039, *2. Venue discovery should be denied.

Plaintiff contends that Alnylam refused to grant an extension to file its opposition to Alnylam's motion to dismiss for improper venue. Not so. Plaintiff never asked for that extension. Rather, Plaintiff requested an agreement on venue discovery (initially seeking seven interrogatories and five depositions), and provided a schedule for such discovery, which included extended filing dates for the parties' briefing. Ex. H. Alnylam responded with a counterproposal for venue discovery, which Plaintiff rejected. D.I. 24, Ex. G. Had Plaintiff simply asked for an extension of time to file its opposition, Alnylam would have agreed. Plaintiff also suggests that Alnylam refused to make Mr. Bossone available for deposition. Again, not true. As is evidenced by the e-mail exchange, Alnylam was amenable to reasonable venue discovery which would, of course, have included the deposition of Alnylam's declarant. *Id*.

V. CONCLUSION

For the foregoing reasons, the Court should grant Alnylam's motion to dismiss for lack of venue or in the alternative transfer this case to the District of Massachusetts.

Dated: February 26, 2025 Respectfully submitted,

/s/ Samoneh Schickel

Samoneh Schickel Texas Bar No. 24097911 McDermott Will & Emery LLP 300 Colorado Street, Suite 2200 Austin, TX 78701

Tel.: (512) 726-2600 Fax: (512) 532-0002

William G. Gaede, III (Admitted Pro Hac Vice) McDermott Will & Emery LLP 415 Mission Street, Suite 5600 San Francisco, CA 94105 (650) 815-7400

Sarah Chapin Columbia (Admitted Pro Hac Vice)
Sarah J. Fischer (Admitted Pro Hac Vice)
McDermott Will & Emery LLP
200 Clarendon Street, Floor 58
Boston, MA 02116-5021
(617) 535-4000

Mandy H. Kim (Pro Hac Vice Pending) McDermott Will & Emery LLP 18585 Jamboree Road, Suite 250 Irvine, CA 92612-2565 (949) 757-6061

CERTIFICATE OF SERVICE

I hereby certify that the foregoing is being served via the Court's CM/ECF system on February 26, 2025, on all counsel of record who consent to electronic service.

By: <u>/s/ Samoneh Schickel</u> Samoneh Schickel